24. (New) The substantially purified nucleic acid molecule according to claim 23, wherein said promoter region comprises a CAAT cis element and a TATA cis element and an additional cis element.

Remarks

1. Support for the Amendments

Non-elected claims 17 and 18 have been canceled, claims 1, 4 and 9 have been amended and claims 19-24 have been added. Support for the foregoing claim amendments and new claims may be found throughout the specification, for example at page 16, line 10 through page 19, line 6, at page 22, line 10 through page 23, line 6, and in the original claims. The specification has been amended to explicitly reference the Sequence Listing on computer readable form in the present application and to comply with the requirements of 37 C.R.F. § 1.821 through § 1.825. No new matter enters by these amendments.

2. Rejection of Claim 9 Under 35 U.S.C. § 112, Second Paragraph, for Indefiniteness

The examiner has rejected claim 9 under 35 U.S.C. § 112, second paragraph, as being indefinite. Office Action at page 3. The basis for the Examiner's rejection is that there is insufficient antecedent basis to support the limitation "the first nucleic acid sequence" as recited in claim 9.

Applicant respectfully disagrees as a common-sense reading of the claim provides support for the term "first nucleic acid sequence". However, to facilitate prosecution, Applicant has amended claim 9. As such, the rejection under 35 U.S.C. § 112, second paragraph, has been rendered moot and withdrawal of this rejection is respectfully requested.

3. Rejection of Claims 1-9 and 16 Under 35 U.S.C. § 101

Claims 1-9 and 16 have been erroneously rejected under 35 U.S.C. § 101 for allegedly not being supported "by either specific and/or substantial utility or a well

established utility". Office Action at page 3. The Examiner acknowledges that Applicant has disclosed several utilities for the nucleic acid molecules of the present invention, for example, to detect the presence or absence of polymorphisms, as probes for expression profiling, or as tools for screening possible herbicide compounds. *Id.* at pages 3-4. However, the Examiner contends that none of the utilities disclosed in the present application satisfy 35 U.S.C. § 101 because "[t]he nucleic acids as disclosed, do not provide to one of ordinary skill in the art, what the presence or absence of the claimed nucleic acids would be useful for." Office Action at page 4.

As Applicant has previously stated, the "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...where specific benefit exists in currently available form." *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicant has met this part of the bargain – the present specification discloses nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, for example use to identify a polymorphism in a population of soybean plants. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit.

The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide <u>one</u> identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The courts have expressed a test for utility that hinges on whether an invention provides an "identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). For analytical purposes, the requirement for an "identifiable benefit" may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or

unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or "substantial" benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

The present specification discloses several uses for the claimed nucleic acid molecules, including use a nucleic acid molecule markers and probes (*see, e.g.*, specification at page 1, lines 17-27, at page 12, lines 12-18, and at page 35, line 10 through page 41, line 26); to identify and obtain nucleic acid homologues (*see, e.g.*, specification at page 30, line 20 through page 31, line 6); in physical mapping to identify clones and produce contigs (*see, e.g.*, specification at page 42, line 1 through page 46, line 20), to identify the presence or absence of a polymorphism (*see, e.g.*, specification at page 47, line 17 through page 54, line 16); to map mutigenic traits (*see, e.g.*, specification at page 56, line 7 through page 58, line 8); use to transform plants and other organisms (*see, e.g.*, specification at page 59, line 7 through page 68, line 6); and use to overexpress or suppress a desired protein (*see, e.g.*, specification at page 75, line 24 through page 78, line 11).

The Examiner acknowledges that the nucleic acids of the present invention may be used as probes, to detect the presence or absence of polymorphisms, and in expression studies, however the Examiner denigrates these utilities by claiming they are not "useful" because they are applicable to any piece of a nucleic acid in general. *See* Office Action at pages 5-7. Furthermore, the Office Action alleges that "[t]he Applicants have failed to disclose such immediate benefit other than a laundry list of possible benefits that a nucleic acid could be used for." Office Action at page 6. This is not correct. The claimed nucleic acid molecules are particularly useful, for example, to identify markers and isolate promoters in *Glycine max*. *See, e.g.*, specification at page 12, lines 12-18.

Despite Applicant's disclosure, the Examiner maintains that Applicant has not given any immediately apparent benefit, substantial or real-world utility for the claimed nucleic acids. Office Action at page 4. In short, the Examiner appears to be arguing that the disclosed utilities are not legal utilities simply because other molecules can be used for the same purpose. That position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result..."). Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. That position must be rejected as it requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933).

Moreover, it is factually incorrect that this use is not "specific" to the claimed nucleic acids. Among the several uses disclosed for the claimed nucleic acid molecules in the present application, the claimed nucleic acid molecules, for example, a particularly appropriate and demonstrably useful starting point for a chromosome walk to isolate a promoter that is active in soybean plants. Specification at page 42, lines 1-17. A random nucleic acid molecule does not provide an equally good starting point to isolate such a promoter. Furthermore, even if a random nucleic acid molecule provided a <u>better</u> starting point than the claimed nucleic acid molecules, it would not obviate the utility of the claimed nucleic acid molecules. An invention may be "less effective than existing devices but nevertheless meet the statutory criteria for patentability." *Custom Accessories, Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 960 n.12, 1 U.S.P.Q.2d 1196, 1199 n.12 (Fed. Cir. 1986).

Applicant has disclosed several specific, substantial and credible utilities for the claimed nucleic acid molecules. Any <u>one</u> of these utilities is enough to satisfy the requirements of 35 U.S.C. § 101. Because Applicant need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the rejection under

Section 101 is incorrect and should be reversed. Reconsideration and withdrawal of this rejection are respectfully requested.

4. *Rejection of Claims 1-9 and 16 Under 35 U.S.C. § 112, First Paragraph, Enablement*

Claims 1-9 and 16 were rejected under 35 U.S.C. § 112, first paragraph, as not enabled by the specification, because the claimed nucleic acid molecules allegedly lack utility and therefore cannot be enabled. Office Action at page 8. This rejection is erroneous and has been overcome by the arguments stated above regarding utility because it is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection must be withdrawn as improper. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement). Thus, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, are respectfully requested.

5. *Rejection of Claims 1-9 and 16 Under 35 U.S.C. §112, 1st Paragraph: Written Description*

Claims 1-9 and 16 have been erroneously rejected under 35 U.S.C. § 112, first paragraph, for allegedly not being described in the specification "in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention". Office Action at page 8. The Examiner does not dispute that Applicant had possession of and has adequately described the claimed SEQ ID NOs. Final Office Action mailed August 29, 2001, at page 6. However, the Examiner maintains that the claims fail to meet the written description requirement.

The first basis for the Examiner's rejection is that SEQ ID NOs: 1 through 10 do not contain a complete open reading frame and the claims "recite the use of second nucleic acids that **comprise** the SEQ ID numbers, reading on the use of second nucleic acids that would be a full-length cDNA and possibly a gene". Office Action at page 9 (emphasis in original). The second basis for the Examiner's rejection is that the claims are drawn to a nucleic acid that hybridizes to a second nucleic acid and "because the second nucleic acid does not contain a full open reading frame, the claims would read on a full-length cDNA sequences as well as gene sequences that would hybridize to the second nucleic acid." *Id.*

This argument flies in the face of the existing patent jurisprudence. It is well-established law that use of the transitional term "comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986). The very nature of "unspecified ingredients" is that they are not specified or described. The Examiner attempts to turn the legal meaning of "comprising" on its head by requiring Applicant to describe hypothetical claim elements. Applicant's claims do not recite open reading frames and, accordingly, need not describe them. Applicant need only describe the claimed invention, and he has done so in the present application.

As Applicant has previously stated, the purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject matter, *i.e.*, to ensure that the inventor actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventor had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at

1584. A person of ordinary skill in the art, *e.g.*, a molecular biologist, would, after reading the present specification, understand that Applicant had possession of nucleic acid molecules comprising nucleic acid sequences selected from the group of SEQ ID NO: 1 through SEQ ID NO: 10, nucleic acid molecules that hybridize to the claimed SEQ ID NOs, and vectors comprising the claimed SEQ ID NOs, and therefore, the claimed invention.

Applicant's present disclosure not only provides the nucleic acid sequences required by the claims (*i.e,* SEQ ID NOs: 1-10), but further describes that the claimed nucleic acid molecules may include the recited sequence with additional sequences, for example, vectors comprising the claimed nucleic acid molecules (specification at page 59, line 7 through page 68, line 6), and extra nucleotides or detectable labels added to the claimed nucleic acid sequences (specification at page 13, lines 15-25). The specification also describes, for example, nucleic acid molecules comprising microsatellites and single nucleotide polymorphisms (SNPs) and methods to identify sequences containing them (specification at page 16, line 10 through page 19, line 6, and at page 89, line 1 through page 92, line 13 (Example 3)), methods for identifying nucleic acid molecules comprising promoter regions and other regulatory elements (specification at page 22, line 10 through page 29, line 8), nucleic acid molecules comprising nucleic acid sequences having conservative substitutions (specification at page 31, lines7-20), fusion protein or peptide molecules or fragments thereof encoded by the nucleic acid molecules of the present invention (specification at page 33, lines 1-24), plant and other homologue proteins (specification at page 29, lines 11 through page 31, line 6), site directed mutagenesis of the claimed nucleic acid molecules (specification at page 58, line 9 through page 59, line 2), references describing the construction, manipulation and isolation of nucleic acid macromolecules (specification at page 79, lines 12-20) and construction of BAC libraries using the claimed nucleic acid molecules (specification at page 83, line 17 through page 88, line 27 (Examples 1-2)). Despite the numerous variations described for the claimed nucleic acid molecules in the present specification, the Examiner maintains that the claims are "improperly described under 112, first paragraph". Office Action at page 9.

The Examiner appears to assert that each nucleic acid molecule within a claimed genus must be described by its complete structure. This assertion is unfounded. The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Applicant has satisfied that test for written description.

In particular, Applicant has disclosed common structural features, for example the nucleotide sequences of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, etc. The respective common structural feature (the nucleotide sequences of SEQ ID NO: 1 through SEQ ID NO: 10) is shared by every nucleic acid molecule in the claimed genera, and it distinguishes the members of the claimed genera from non-members. For example, if a particular vector contains the nucleotide sequence of SEQ ID NO: 1, then it is a member of the claimed genus of vectors comprising a nucleic acid sequence of SEQ ID NO: 1.[1] If a particular vector does not contain the nucleotide sequence of SEQ ID NO: 1, then it is not a member of that claimed genus. *See* claim 8. The presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such – it either contains the nucleotides of SEQ ID NO: 1 or it does not.

Moreover, closely related nucleic acid molecules falling within the scope of claim 1 and its dependents are readily identifiable - they either hybridize under the claimed conditions to SEQ ID NOs: 1-10 (or complements thereof) or they do not. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification.

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[1] The same argument applies with equal force to every genus of the claimed nucleic acid molecules. For example, if a vector contains the nucleotide sequence of SEQ ID NO: 2, then it is a member of the claimed genus of vectors comprising a nucleic acid sequence of SEQ ID NO: 2. *See, e.g.*, claim 8.

In light of the detailed disclosure of the present application, one skilled in the art, after reading the present specification, would clearly know if a nucleic acid molecule contains one of the recited nucleotide sequences. Thus, claims 1-9 and 16 are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed. Reconsideration and reversal are respectfully requested.

6. Rejection of Claim 1 Under 35 U.S.C. § 102

Claim 1 has been erroneously rejected under 35 U.S.C. § 102(b) over Laten *et al.* Office Action at pages 10-11. According to the Examiner, Laten discloses a nucleic acid sequence that exhibits 94.2% local similarity to SEQ ID NO: 8 and would therefore hybridize under the claimed conditions. Applicant respectfully disagrees that the small region of homology cited by the Examiner (308 basepairs having 94.2% identity) is sufficient to permit hybridization of the entire Laten sequence (4190 total basepairs having only 58.3% identity) under the claimed conditions. However, in order to facilitate prosecution, Applicant has amended claim 1. As such, the rejection under 35 U.S.C. § 102(b) over Laten is rendered moot and withdrawal of this rejection is respectfully requested.

7. Double Patenting

Claims 1-7 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-7 of copending Application No. 09/521,640. According to the Examiner, SEQ ID NOs: 1-10 of the present application are identical to SEQ ID NOs: 141334-141343 of the '640 application.

Applicant respectfully points out the a Restriction Requirement was issued in the '640 application on September 19, 2001, in which a sequence election requirement was made. *See* Office Action mailed September 19, 2001, at page 4. In response, the applicants in the '640 application elected SEQ ID NO: 2 for prosecution on the merits. *See* Response filed October 17, 2001, at page 4. Furthermore, the claims in the '640 application were amended to recite only the elected sequence of SEQ ID NO: 2. *See* Response filed April 1, 2002, at page 3.

As such, the claims 1-7 of the present application are directed to different subject matter than claims 1-7 of co-pending Application No. 09/521,640. Thus, the provisional double patenting rejection is improper and must be withdrawn. However, if the Examiner imposes a double-patenting rejection, upon the indication of allowable subject matter, Applicant will submit a terminal disclaimed as appropriate.

Conclusion

In view of the above, the presently pending claims are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdrawal the outstanding rejections and pass the application to issue. The Examiner is encouraged to contact the undersigned with respect to any unresolved issues remaining in this application.

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicant does not believe that any fees in addition to those provided for in the accompanying documents, are due at this time. However, if any fees under 37 C.F.R. 1.16 or 1.17 are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Deposit Account No. 50-2387, referencing docket number 16517.142.

Respectfully submitted,

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Marked-Up Version of Amended Specification

At page 90, lines 1 through 19:

The above protocols are used to develop primers from Sequence id GM_M02_A2_B07_MR_MR containing the following nucleotide composition **(SEQ ID NO: 36936)**:

AGGCGTTTTNCCTTGATACCTTCGNAGGTCCANCCTTTTNCTTGCTGTATCGA
CTCATTAACACCAAGCTCGGTGAGCACTCTGAAGATTATGACAACTTTCGNTG
ATCTTTTTGTCATCGATATTNTAGNAGAGACCAATCTTTCTTCTTCAAATGTCG
CTCATGATATTTATTGTAATTATCTTCAATGTATGTCCAAAAAGTTAACCTTTT
TTGGACCCCCACAATAGAAATCTTTGAAATATTTAGCCATGTGTTGGCAAGCC
ATTCATATTTCTTTGCGGAGAAACATGATCTATTGTGTCTTTCGGATGCTTCTT
CTATGTcttcttcttcttcttcttcttcttcttcttcttCATTGACCACAATATTATCCAACTCAACTTA
GGTGCAAAATGGTGGAATTTGAGACTTTGACGCANAGTCAGATGGTGCGTCA
TGCTCTTTCATTACATTGGACATCATNTACTACCCTTTGAAGACCCTCGATCC
ATGGAAGGGTTAATTGGTG

This sequence contains CTT dinucleotide repeats with a repeat unit of 11. Using the Primer 3 program, two primers are selected: SER157F GTGTCTTTCGGATGCTTCTTCT **(SEQ ID NO: 36937)** and SER157R CACCATTTTGCACCTAAGTTGA **(SEQ ID NO: 36938)**. When these two primers are used to amplify genomic DNAs from eight different varieties, Minsoy, Noir, PIC, HS-1, A3244, H6686, A0868 and H5088, three alleles are detected. Sizes of these alleles ranged from 80 to 110 **[bp] base pairs**. The size variation in the PCR products result from repeat numbers in different varieties.

Marked-Up Version of Amended Claims

1. (Twice amended) A substantially purified nucleic acid molecule, said nucleic acid molecule capable of specifically hybridizing, under conditions of 6.0 x sodium chloride/sodium citrate (SSC) at about 45°C, followed by a wash of 2.0 x SSC at 50°C, to a second nucleic acid molecule having a nucleic acid sequence selected from the group consisting of **[SEQ ID NO: 1 through SEQ ID NO: 10]** **SEQ ID NOs: 1, 2, 3, 4, 5, 6, 7, 9, 10** and complements thereof.

4. (Twice amended) The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule comprises a nucleic acid molecule having a nucleic acid sequence selected from the group consisting of **[SEQ ID NO: 1 through SEQ ID NO: 10]** **SEQ ID NOs: 1, 2, 3, 4, 5, 6, 7, 9, 10** and complements thereof.

9. (Twice amended) The vector according to claim 8, wherein said **nucleic acid sequence is a first nucleic acid sequence, and wherein said** vector further comprises a second nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 10, wherein said second nucleic acid sequence is not identical to **[the]** **said** first nucleic acid sequence.